A I D S TREATMENT N E W S

Issue Number 395
October 31, 2003

Published 18 times a year by
John S. James
AIDS Treatment News
1233 Locust St., 5th floor

Contents

AIDS Treatment News

Subscription and Editorial Office:
AIDS Treatment News
Philadelphia FIGHT
1233 Locust St., 5th floor
Philadelphia, PA 19107
800-TREAT-1-2 toll-free U.S. and Canada
fax: 215-985-4952
email: aidsnews@aidsnews.org

Editor and Publisher: John S. James
Reader Services: Allison Dinsmore

Statement of Purpose:
AIDS Treatment News reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations that work for them. *AIDS Treatment News* does not recommend particular therapies, but seeks to increase the options available.

Subscription Information: Call 800-TREAT-1-2

Businesses, Institutions, Professional offices: $325/year. Includes early delivery of an extra copy by email.

Nonprofit community organizations: $150/year. Includes early delivery of an extra copy by email.

Individuals: $140/year, or $80 for six months.

Special discount for persons with financial difficulties: $54/year, or $30 for six months. If you cannot afford a subscription, please write or call.

Outside the U.S., Canada, or Mexico, add airmail postage of $20/year, or $10 for six months.

Back issues, and discounts for multiple subscriptions, are available; contact our office for details.

Please send U.S. funds: personal check or bank draft, international postal money order, or travelers checks. VISA, Mastercard, and purchase orders also accepted.

looks at some of the medical, financial/legal, vocational, and psychosocial issues involved -- and how to get help with them (interview, part 1 of 2).

Lexiva™ (Fosamprenavir) Approved

On October 20 the U.S. Food and Drug Administration approved the protease inhibitor Lexiva (generic name fosamprenavir, also called 908). Lexiva is converted into amprenavir (Agenerase), a previously approved protease inhibitor, in the body. Lexiva is easier to take than amprenavir because of the smaller pill burden (usually 4 pills a day including the ritonavir, vs. 16 pills a day for Agenerase), and lack of food restrictions. It was developed by GlaxoSmithKline and Vertex Pharmaceuticals Incorporated.

Persons taking Lexiva should review the safety and other patient information, including dangerous interactions with certain other drugs. Information for patients (and prescribing information for physicians) is at http://www.lexiva.com.

For More Information

For a brief review by the FDA of the pivotal clinical trials, see:
http://www.thebody.com/fda/lexiva.html?m18
(or search for Lexiva on http://www.thebody.com)

For Glaxo's review, see:
http://www.gsk.com/press_archive/press2003/press_10212003a.htm

For an extensive review by the AIDS treatment activist organization TAG (Treatment Action Group), supporting approval -- but only when Lexiva is "boosted" with a low dose of ritonavir to increase blood levels of Lexiva -- see:
http://www.aidsinfonyc.org/tag/tx/fosamprenavir.html

Warning Against Tenofovir+ddI+3TC, and "Triple Nuke" Combinations

On October 14, 2003 Gilead Sciences warned health care professionals against a using ddI plus 3TC plus tenofovir combination, after many patients on that regimen failed to control the virus and developed mutations to the drugs. The "dear doctor" letter, "High Rate of Virologic Failure in Patients with HIV Infection Treated with a Once-Daily Triple NRTI Regimen containing Didanosine, Lamivudine, and Tenofovir" is on the FDA Website,
http://www.fda.gov/medwatch/SAFETY/2003/viread_deardoc.pdf

The letter also cautioned against all-NRTI regimens in general, as three other such regimens showed disappointing antiviral results in clinical trials.

Clinton Foundation Gets Big Price Reduction -- to 40 Cents a Day for Three-Drug Combination

On October 23 the Clinton Foundation HIV/AIDS Initiative announced that four generic pharmaceutical manufacturers had agreed to reduce prices for some African and Caribbean countries to about $140 per year for triple-drug antiretroviral therapy -- less than 40 cents a day. The reductions were possible because business executives volunteering with the Foundation helped reduce raw-materials cost, in part by developing a much larger market for the drugs in poor countries; the Foundation is also developing funding for infrastructure. The drugs are nevirapine, 3TC, and either AZT or d4T; the combinations will be manufactured in a single pill taken twice a day.

UNAIDS (the Joint United Nations Programme on HIV/AIDS) applauded the announcement in an October 23 press statement, and noted that it would help the "3x5" initiative of the World Health Organization and UNAIDS (the effort to get treatment access to 3,000,000 people by 2005), and the work of the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

For more information see "Clinton Program Would Help Poor Nations Get AIDS Drugs," by Mark Schoofs, *The Wall Street Journal*, October 23, 2003, and "Clinton Group Gets Discount for AIDS Drugs" by Lawrence Altman, *The New York Times*, October 23.

Retroviruses Conference Reminder: Community, Press Deadlines November 14

November 14 is the deadline for both community scholarship applications and community newsletter press applications, for the important 11th Conference on Retroviruses and Opportunistic Infections (February 8-11, 2004, in San Francisco). The scholarship information was not on the site as we went to press on November 1.

All other press (newspapers, TV, etc.) must register by January 7; registration may close earlier if the slots fill up. No

press registration will be allowed onsite.

The "community scholarship" route is the only way for many people with HIV to get into the conference -- even if they do not need the money. This conference is only open to researchers and a few others; one cannot get in just by paying admission.

Remember that after your scholarship or press application is accepted, you will still need to complete the registration and housing process by a later deadline.

More information can be found at: http://www.retroconference.org.

Thailand Conference Submission Deadlines (Theme: Access for All)

by John S. James

The XV International AIDS Conference -- organized by the International AIDS Society, the Thai Ministry of Public Health, UNAIDS, and four AIDS organizations, will take place July 7-16, 2004 in Bangkok, Thailand. A recent email alert noted several deadlines; we added some others from the conference Website to this list. All the dates below are 2004. (One deadline, for commercial exhibits, is December 31, 2003.)

January 14: Abstract submission by paper forms and disk or CD must be received (note online deadline a week later).

January 21: Online abstract submission deadline (Online is preferred; in case of last-minute submission, note time zones.)

February 2: Skills-building workshop submissions due.

February 2: Registration fee goes up.

February 2: Scholarship applications must be received.

February 2: NGO exhibition request deadline.

April 1: Deadline for guaranteed hotel reservation.

May 26: Late-breaker abstract submission (online only).

Note that there may be no onsite registration.

For complete information see the conference Web site: http://www.ias.se/bangkok/start.aspx

Comment: Protests on Thailand

There have been protests against holding the conference in Thailand, due to what most observers believe is the government-sponsored killings of more than 2,000 suspected drug dealers or users, especially in February, March, and April 2003. For more information see "A Wave of Drug Killings is Linked to Thai Police," *New York Times*, April 8, 2003. Other major references, including Amnesty International and *Time Magazine*, can be found by a search (for example, for "Thailand drugs killing" [without the quotes] at http://www.google.com). Also, search Google for "Thai Drug Users Network" (include the quotes in this search).

The major international AIDS conferences take four years to organize, and this one would have been almost

impossible to move in the time available.

Comment: Access for All

AIDS Treatment News proposed the theme "access for all" for activists at the Vancouver international conference in 1996 (article is at http://www.aids.org/atn/a-248-10.html). We are glad to see this theme today at a world AIDS conference.

The good news on HIV treatment access is that pilot programs are now starting in many poor countries around the world, potentially offering treatment to many people for the first time. The challenge is finding the funding to go beyond pilot programs. At this time most rich countries are neglecting the global epidemic, in their focus on Iraq and on their relationship with the only superpower.

Clinical Trials Forum: World AIDS Day (December 1), Boston

On World AIDS Day (December 1, 2003) Search for a Cure will hold a free community forum on clinical trials for persons with HIV -- including information on hepatitis and other co-infections, nutrition, microbicides, and other related topics. People can speak with researchers running the trials and with volunteers currently in studies, at information tables for many trials now open in New England. Experts will discuss what to consider when thinking about volunteering for a trial. Search for a Cure will distribute a manual on major HIV clinical trials in New England, and how to find out about trials elsewhere. A free dinner is included in this program.

Many AIDS trials are being seriously delayed because not enough patients enroll. Search for a Cure hopes to help increase enrollment when possible. Other organizations may want to try similar programs in their cities.

This free consumer forum will start with dinner from 5:30 to 6:30, followed by the program from 6:30 to 8:30, December 1, 2003, at The Ballroom at Longwood Towers, 20 Chapel St. in Brookline (across from Longwood D Line T stop). Call Search For A Cure at 617-536-2474 for reservations, and for directions or other information.

Returning to Work After Disability; What You Should Know

Interview with Eric Ciasullo, manager of the San Francisco Department of Public Health's HIV/AIDS Return to Work Initiative. Ciasullo is currently Chair of the Board of Directors of the National Association of People with AIDS (NAPWA), and was recently appointed to the California State Rehabilitation Council.

by John S. James

Tens of thousands of people with HIV want to return to work at least part time but are afraid of losing medical benefits, or losing disability income and then being unable to work in the future. Recent Federal legislation has reduced this problem, but information, planning, and expert advice are still essential. Many people need retraining or new skills in order to re-enter the workforce successfully; often excellent opportunities are available through state government rehabilitation departments, but the HIV world has not been familiar with these services. Others ran up huge tax, student loan, credit card, or other debts while trying to stay alive; they may be able to renegotiate some of these debts while they are disabled, and should do what they can to clean up these problems before leaving disability and returning to work.

Recently, Governor Gray Davis of California appointed AIDS advocate Eric Ciasullo to the California State Rehabilitation Advisory Council, which oversees the California Department of

Rehabilitation. Mr. Ciasullo has long been active in HIV prevention, housing, and other services -- most recently in helping people with HIV consider returning to work, and getting any help they need to return to work successfully. He himself has been on AIDS disability and is now working full time for the San Francisco Department of Public Health. *AIDS Treatment News* interviewed him on October 10, 2003, in San Francisco.

In the interview Mr. Ciasullo suggested a number of resources, most of them available on the Web. They are listed in a separate section below. In some areas it may be difficult to find good advice on benefits and other issues in planning for returning to work. You might start by asking your doctor for a referral, or asking a case manager or social worker if they could help, or could refer you to an expert. You might check with your local health department, especially if you do not have a case manager already. Some questions could be answered by the National STD/AIDS Hotline, 800-342-2437, 24 hours a day seven days a week. This hotline also has a number for Spanish speakers, and TTY access for the hearing impaired; TTY is 800-243-7889 Monday through Friday 10 a.m. to 10 p.m. Eastern time.

In addition, the Social Security Administration funds organizations in every state to assist beneficiaries in making choices about work (see the Social Security service providers list at the end of this article). The best benefits advisers in an area may work out of other offices as well. Before talking with an expert you might want to read background information -- for example, see the Web sites in the Resources section at the end of this article.

* * *

ATN: Could you give some examples showing the kinds of issues people face when leaving disability and returning to work?

Eric Ciasullo: Everybody's situation is so different. It is hard to show a few representative examples, so much as dynamics that occur across the board but to different degrees. For instance, in San Francisco we've found that more than half of those interested in work want to do something very different from what they did before disability. Many people want to do work that feels meaningful. Many of us have been recipients of social services and want to give something back. We tend to be less tolerant of activity that is not directed to a human bottom line.

Because HIV disproportionately affects people based on race, education and class, many of us were untrained or under-trained workers. We may never have really been in the workplace, or if we have, only as casual labor. We may have worked in what some folks refer to as the "underground" or unregulated economy. We may need to be trained in work that is not physical labor, or where we will not be on our feet most of the time, because there are still a lot of physical considerations with HIV. We may need reasonable accommodations -- like being able to sit down, take frequent breaks, nap in the afternoon if necessary, or take more bathroom breaks than some of our co-workers. The more skilled we become as workers, the more likely we are to work for employers that are able to make these kinds of accommodations.

ATN: What about returning to work at least part time, earning income and being able to keep medical benefits, or to go back on disability if necessary?

Ciasullo: Recent changes in Federal law have made this easier [see discussion in the "Financial and Legal..." section below]. But still it is very important for people considering work to meet with some kind of benefits counselor or advisor, so that they understand the particularities of their situation, and the impact of work on benefits.

Disabled workers with HIV are usually on SSI or SSDI. These two Federal programs work in completely different ways. The incentives are totally different. The attachment to health care is totally different. State by state access through Medicaid is totally different. Of course, most people with HIV don't have private disability policies, but even those policies are all written differently. Even the earning limits that allow people to access the AIDS Drug Assistance Program (ADAP) are different county by county. That's why it's so important for people to get good information and advice before they make decisions about work.

For many of us who are concerned with helping PLWHA work through their barriers to employment, the Kohlenberg/Goldblum Considering Work Model is helpful in describing four overlapping arenas that need to be addressed: Medical, Financial/Legal, Vocational, and Psychosocial. [See the Considering Work model, in the Resources section below.]

Medical Considerations

In the medical arena it's typical for folks to be asking, "am I really well enough to work? What if I have to change meds, or the meds stop working? How will the stress of working affect my health? Will my adherence be compromised -- will I be able to take the medications correctly and consistently? Can I manage my meals around my meds while still working? Will I be able to manage my other daily activities while still working? Is my health stable enough to go back to work, and what will happen if it changes?"

For many of us, health maintenance is a pretty careful and delicate balancing act, and integrating self-care activities with the demands of employment can be a formidable challenge. That's one of the reasons why many of us encourage people to gradually increase their activities: maybe first try creating a sort of "shadow work" schedule of training or volunteer work, then if they can, start working first on a part-time basis.

Financial and Legal -- New Ability to Work and Keep Federal Benefits

In the financial and the legal arena, people are frequently very anxious about what will happen to their financial and health benefits if they start working, particularly if they're not able to maintain their work efforts. Often we had to fight really hard to get benefits, and it's natural that we'd be concerned that even talking about work could jeopardize the essential stability that those benefits provide. In fact, until just recently, work activity *could* trigger a continuing disability review (CDR) of your Social Security benefits. Fortunately, that's no longer the case; the Ticket to Work and Work Incentives Improvement Act of 1999, or TWWIIA, brought important improvements. Some of the most prominent features of the legislation are that a CDR cannot be triggered by work activity, and if a CDR is actually scheduled, the fact that someone is working cannot be used to demonstrate that they are not disabled.

Also, there has been a significant increase in what people can earn on the books, legally, while maintaining all of their SSDI benefits, and/or a portion of their SSI benefits. This is why I always emphasize that part-time employment is something that a lot of us should really consider to improve our financial situations, and to look for some of the social benefits that come from working.

For people whose SSI or SSDI benefits are discontinued due to earnings, there's a five-year period in which the process for getting back on benefits is greatly expedited. The actual rules are quite different for SSI and SSDI, though, so it's very important to find out exactly how the different programs work.

But the anxiety remains -- what happens if I give up my benefits so that I can work, then have to stop working? Some of these concerns are inevitable given the uncertainties in our lives, but some of

them are rooted in old rules that are no longer in place. A lot of folks still have a very limited understanding of what the new work incentives are.

I encourage people considering work entry or re-entry, especially if they have the freedom of some time, to take advantage of training opportunities, to try to be patient enough to look for a job that's going to be rewarding, one that has private group health insurance, and if possible, to find an employer with a private disability insurance policy. With those things in place, the gamble you are making on your health is that if you are able to sustain your efforts for a couple years, should you become disabled and unable to work again, your financial standing will be better than it was before you went back to work. That should be part of the incentive that we're creating for ourselves.

ATN: What about continuing Medicaid and/or Medicare, if someone finally leaves disability and can go back to work but is unable to get insurance through the job?

Ciasullo: Well, the rules are different. Medicaid is attached to SSI, and Medicare is attached to SSDI. Medicare continues for almost 8 years after SSDI benefits have ended. Medicaid is trickier, because it involves both federal and state laws. Under the new Federal work incentives, however, states have the option of providing Medicaid to working people with disabilities whose earnings are too high for them to qualify for Medicaid under other existing rules. The intention -- and we will have to lobby state by state -- is that if I am on SSI and went back to work, I should be able to purchase Medicaid for an affordable price. So if we organize around this effectively, and in this AIDS activists really need to take the lead from our colleagues in the cross-disability community, many of us will have a capacity to buy into a state-sponsored plan even if we're not covered by group health insurance policies.

Vocational Training

If we're honest with ourselves, many of us who are on disability have energy that we could put to productive use. Most of us who aren't desperately fighting for life right now might have some ability to work with some of our time. Many experts believe that work plays a vital role in maintaining our physical and mental health, that it alleviates depression, contributes to a sense that life has meaning, and keeps us engaged as active participants in our communities. Maybe that work won't be paid employment; it may start with sustained activity that benefits other people as volunteer work or an internship, or it may be school and training.

Even those of us who left the workforce with job-related skills might find that the skills we had are out of date or no longer relevant. Some of us aren't able to do the kind of work we previously did, even if we don't need retraining for that job. Or health and stamina, the vagaries of living with the virus, might demand that we limit our activities to part-time employment, or intermittent employment, or a job that is basically sedentary.

The reality is that most of could find real benefit in taking time for ourselves to deal with unresolved issues around basic education, or to get trained or retrained for jobs that make sense for our lives now.

State Departments of Rehabilitation

ATN: I was amazed at the employment help and services a friend of mine was able to get in California. He does not have HIV but was disabled in an automobile accident. With help from the state, he has been able to return to work full time.

Ciasullo: He probably received services from the California Department of Rehabilitation (DOR). Unfortunately most folks in "AIDS World" are unfamiliar with these state agencies (called vocational rehabilitation in some states). Before the recall, Governor Davis named me to the